Quality in Mammography

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Acceptable

- PACS
- Workstations
- Density
- CAD

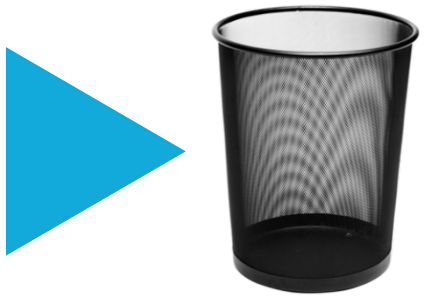
Not Acceptable

Reject Reason

- Typical gantry cannot send rejected images to a different destination

- Digital mammography has removed our ability to retrospectively analyze rejected images:
  - Were the rejections legitimate?
  - Is re-training called for?

- We must change that



Training
40 hr didactic + 25 supervised studies

On-going CE
15 units every 36 mo

Triennial Accreditation
Their skill is judged

Technologist

Weekly QC

Bi-annual Physicist Visit

Triennial Accreditation

Mammo System

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The current process relies on “spot checks”

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If spot checks are sufficient, why do sites fail accreditation?

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Poor Positioning Responsible For Most Clinical Image Deficiencies, Failures

Mammography combines "the science of imaging and the art of positioning" [1]. Although there have been many significant and exciting changes to the technology of mammography since the passage of MQSA in 1999, including the introduction of full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT), one aspect of mammography that remains unchanged and critically important is proper patient positioning.

Positioning is so important because only those portions of the breast which are included on the mammographic image can be evaluated for signs of cancer. Any portion of the breast which is not imaged cannot be evaluated, and cancers in those portions of the breast can be missed. In a 2002 study, the "[s]ensitivity [of mammography] dropped from 84.4% among cases with passing positioning to 66.3% among cases with failed positioning" [2].

Poor positioning has been found to be the cause of most clinical image deficiencies and most failures of accreditation. In 2015, the American College of Radiology (ACR), the largest FDA-approved accreditation body (AB), found that of all clinical images which were deficient on the first attempt at accreditation, 92% were deficient in positioning. Also, in ACR-accredited facilities, 79% of all unit accreditation failures in 2015 were due to positioning. Similar results were noted by the Iowa and Texas state ABs: in 2015, positioning was a cause of 91% of clinical image failures in Iowa and 100% of clinical

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.htm, accessed 2016-09-01

92% of 1st attempt

ACR (2015): clinical image deficiencies were due to positioning

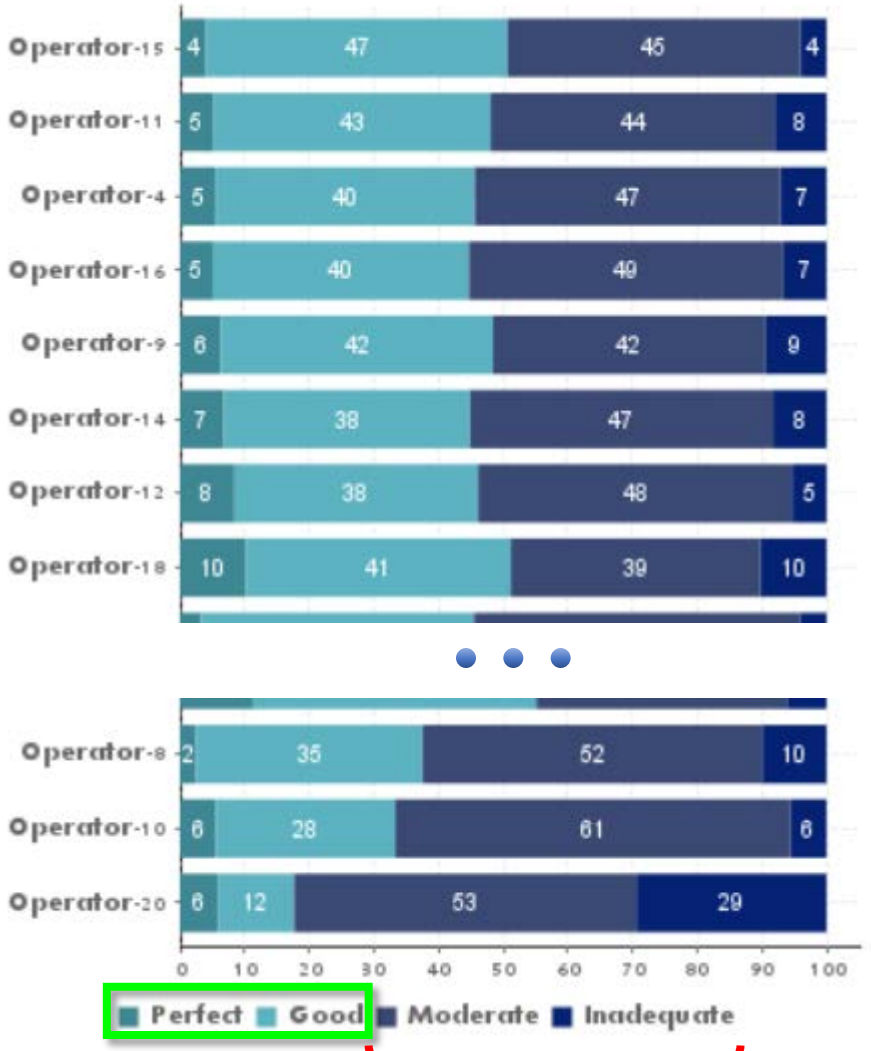
[*images submitted were the result of the facility selecting high quality images specifically for accreditation*]

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.htm, accessed 2016-09-01

ConstantQuality Metrics

- Assess positioning of every mammography image
- Provide daily statistics to chief technologist to drive additional training, as needed
- Form basis for new, stronger quality programs

Image Positioning Score per Tech



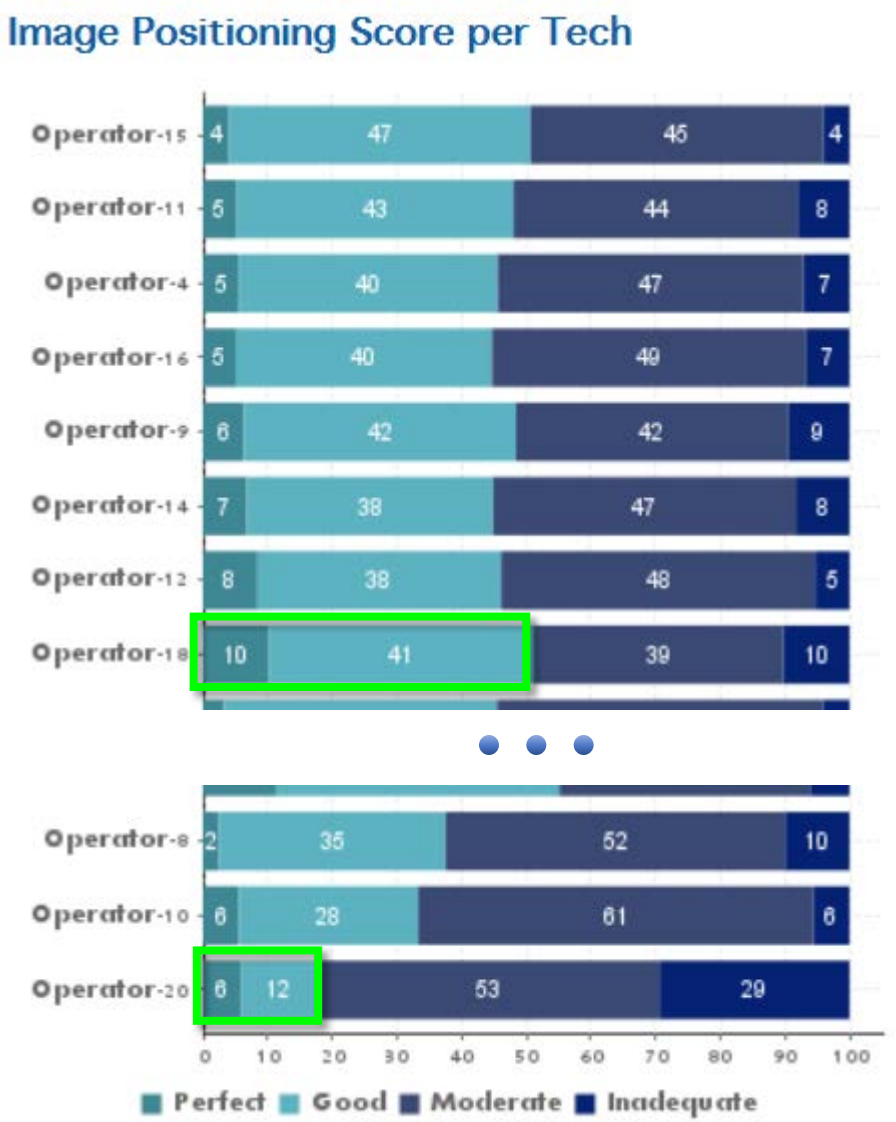
Limited Diagnostic Value

51%

Good or Perfect

18%

Good or Perfect

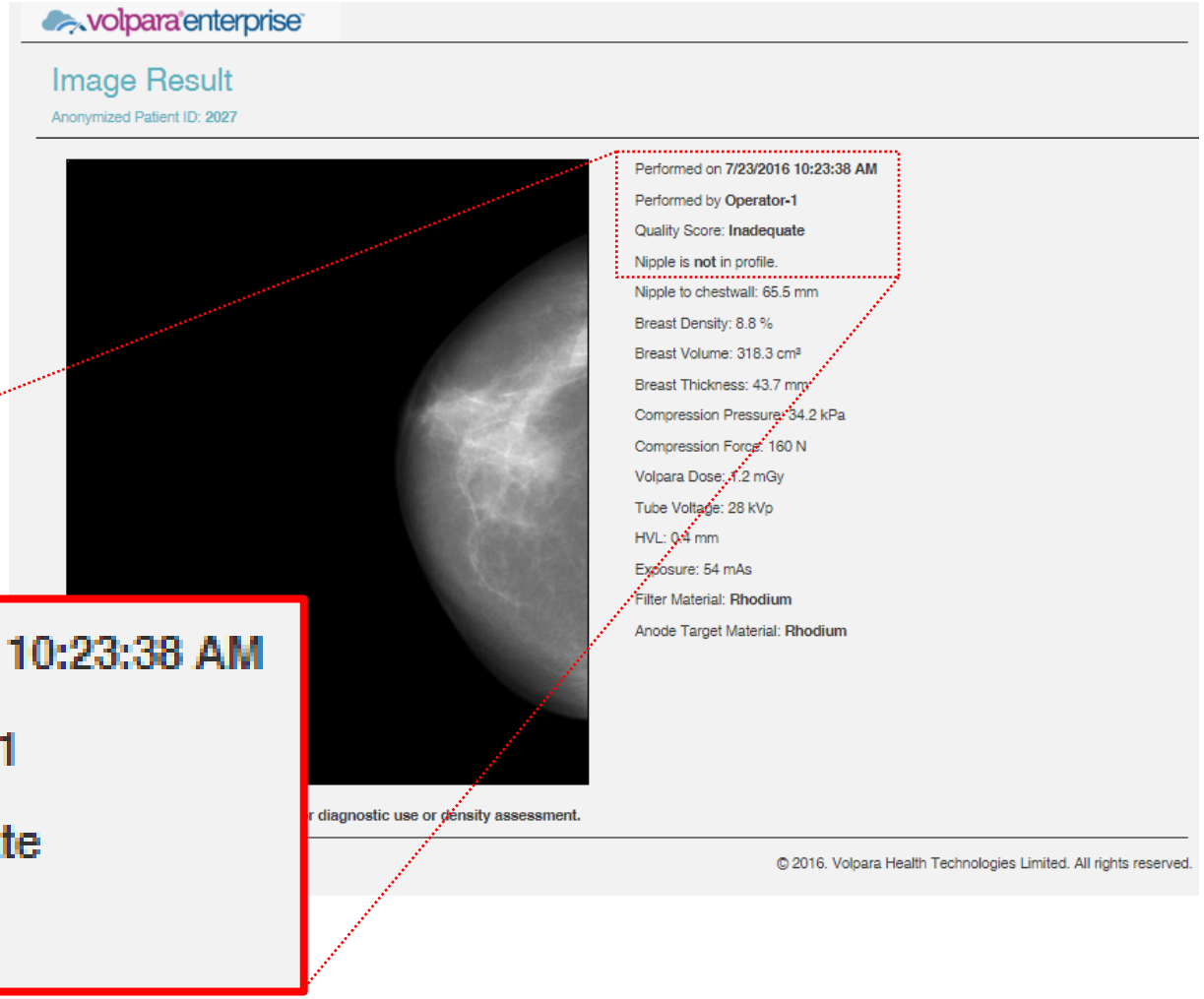


Significant operator variability

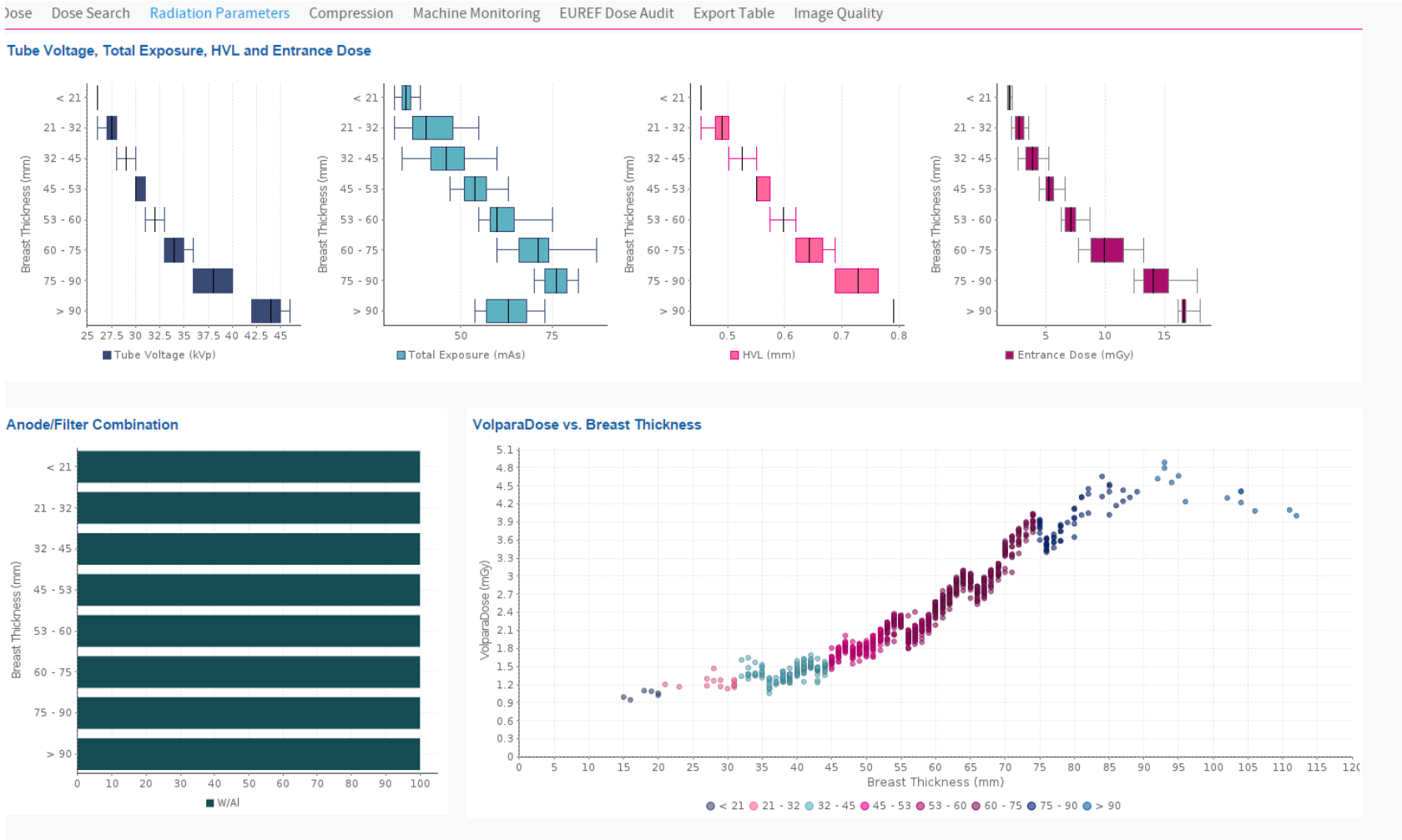
Learning from Issues

Its critical to understand **why** an image or study is **Inadequate**

Looking at statistics and trends lets us re-train techs on the **exact issues** with which they struggle



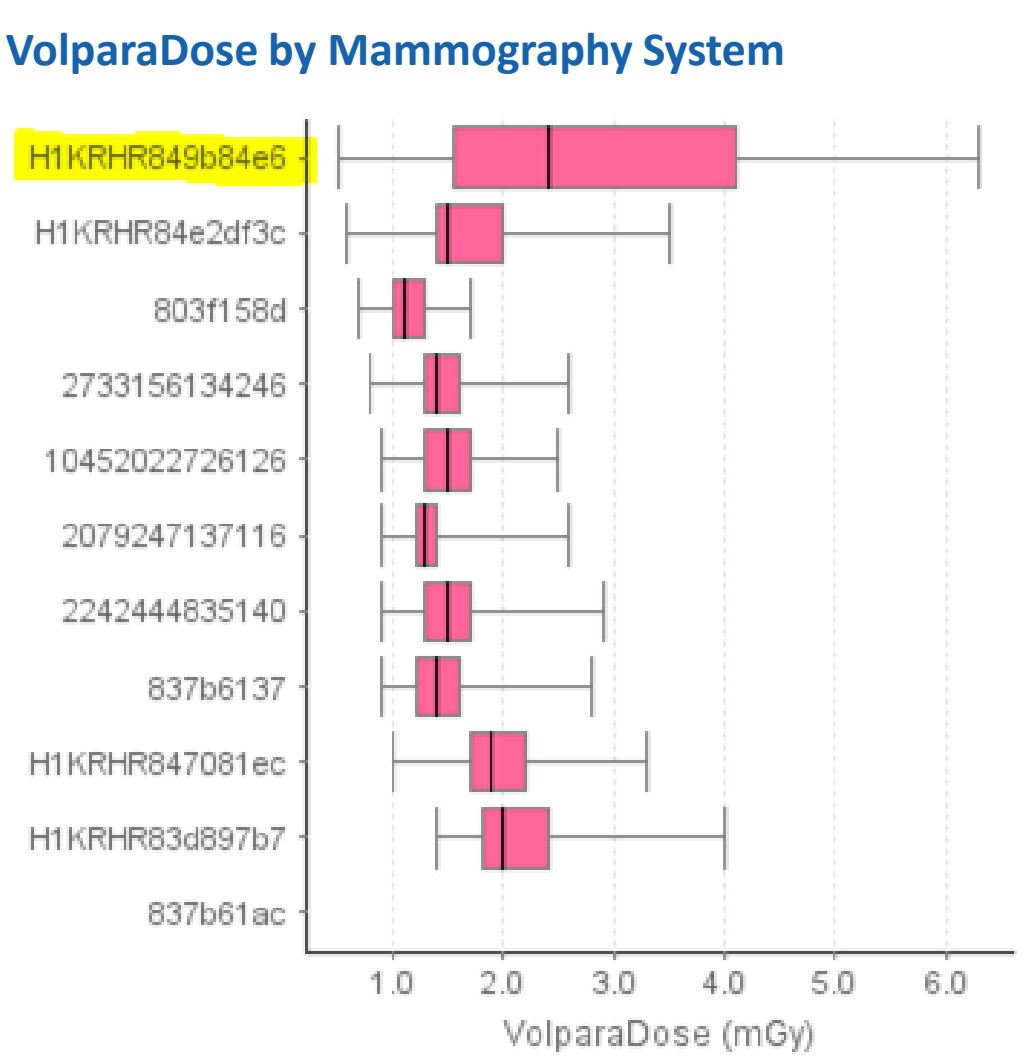
Remote System Monitoring



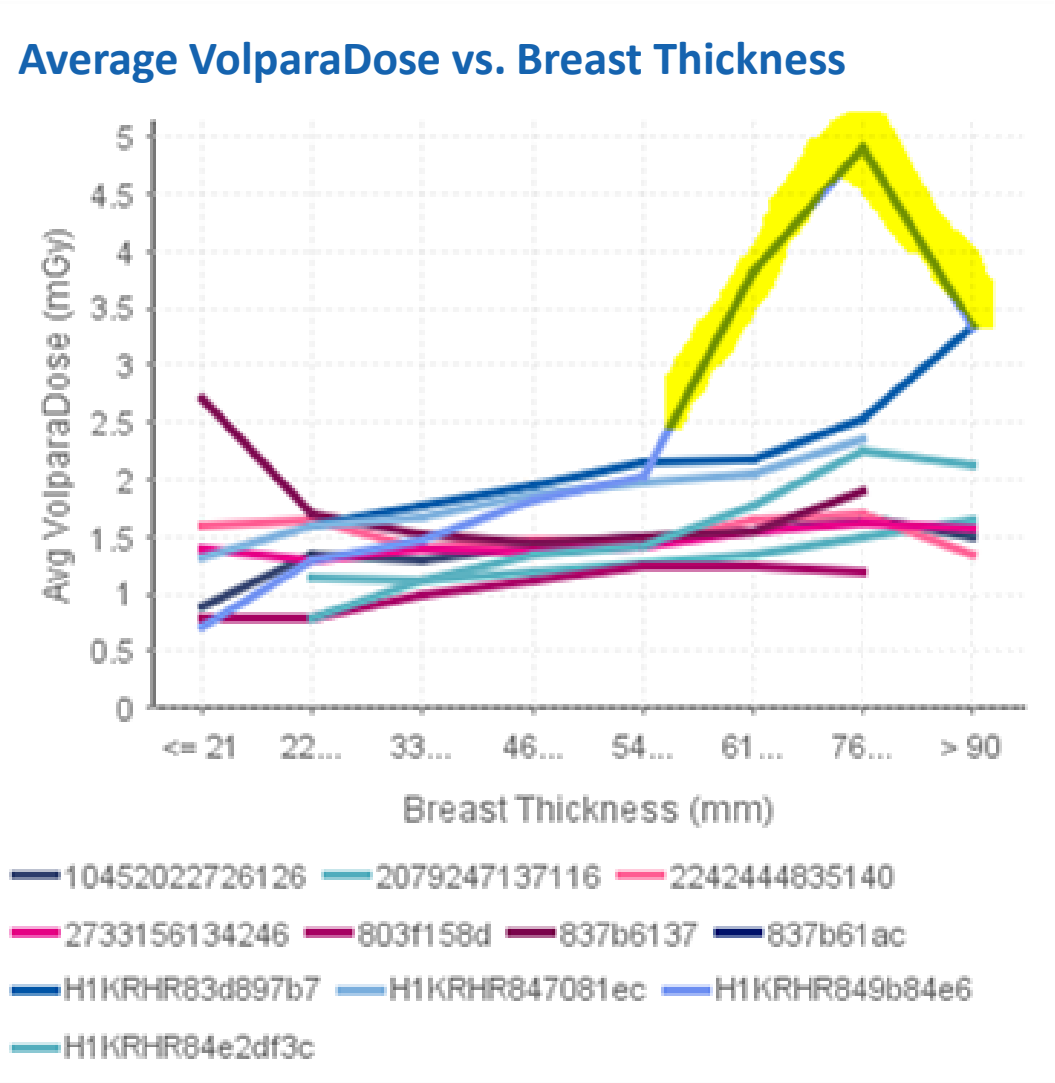
Dynamic monitoring of equipment performance:

- Tube voltage
- Total exposure
- HVL
- Entrance dose
- Anode/filter combination
- Dose vs. breast thickness

Discovery of an Issue



Discovery of an Issue



Solution?

- Recalibrate system
- HVL incorrectly entered

In the end:

- Patients doses were normal
- *Reported* dose was excessive

Demand ConstantQuality!

- Every woman deserves a diagnostic quality mammogram
  - Why wait for the next “spot check”?
  - Check every mammogram and every system – every time!

Thank You